

Remarks/Arguments

Claims 39-43 are pending in this application and are rejected on various grounds. The rejections to the presently pending claims are respectfully traversed.

Priority

The Examiner has not accepted the priority date asserted by the Applicant and does not find the Goddard declaration persuasive for granting the priority date based on the asserted utility of "gene amplification".

Under the 102(a) rejection on page 4, the Examiner points out that "the increased copy number of DNA does not provide a readily apparent use for the PRO211 polypeptide itself, for which there is no information regarding level of expression, biological activity or a specific role in lung or colon cancer". The Examiner concludes that one skilled in the art would not be able to use the PRO211 polypeptide or its antibody and further asserts that the only utility for this polypeptide/ antibody was based on its ability "to inhibit VEGF stimulated proliferation," thereby entitling Applicants to a 2/22/2000 filing date.

Applicants submit that the working hypothesis among those skilled in the art is that, if a gene is amplified in cancer, the encoded protein is likely to be expressed at an elevated level, and hence, such a polypeptide would be useful in detecting cancer. However, increased gene copy number may not *necessarily* result in increased protein expression. To explain polypeptide utility for such circumstances, Applicants have enclosed a Declaration by Dr. Avi Ashkenazi, Ph.D., an expert in the field of cancer biology and an inventor of the present application. As Dr. Ashkenazi explains,

"even when amplification of a cancer marker gene does not result in significant over-expression of the corresponding gene product, this very absence of gene product over-expression still provides significant information for cancer diagnosis and treatment. Thus, if over-expression of the gene product does not parallel gene amplification in certain tumor types but does so in others, then parallel monitoring of gene amplification and gene product over-expression enables more accurate tumor classification and hence better determination of suitable therapy. In addition, absence of over-expression is crucial information for the practicing clinician. If a gene is amplified but the corresponding gene product is not over-expressed, the clinician accordingly will decide not to treat a patient with agents that target that gene product".

In view of the Ashkenazi Declaration which supports utility for the claimed antibodies, Applicants reassert that the present application is entitled to the effective priority date of 10 September, 1998 of application PCT/US98/18824 which establishes specific and credible utility for the anti-PRO211 antibodies claimed. Accordingly, the Examiner is respectfully requested to reconsider and acknowledge this priority date.

Claim Rejections-35 U.S.C. §112

Claims 39-43 are rejected under 35 U.S.C. §112, first paragraph, since allegedly, the claimed invention was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The Examiner alleges that the instant specification as filed fails to describe an antibody that specifically binds to a polypeptide of SEQ ID NO: 2 and that one would not know how to distinguish the antibodies that "bind" SEQ ID NO:2 and those that "specifically bind" to a polypeptide of SEQ ID NO:2. Applicants respectfully traverse this rejection.

In the interest of expediting prosecution in this case, Applicants have amended claim 39 to remove reference to "specific" binding as suggested by the Examiner.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claim Rejections – 112, second paragraph

Claim 39-43 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for recitation of "specifically binds" whose metes and bounds could not be determined from the instant specification.

In the interest of expediting prosecution in this case, Applicants have amended claim 39 to remove reference to "specific" binding as suggested by the Examiner. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claim Rejections – 35 USC §102

Claims 39-43 were rejected under 35 U.S.C. 102(a) as being anticipated by WO99/58660 because the effective filing date awarded to the instant application was 2/22/00.

As discussed above under priority, the present application is entitled to an effective filing date of 10 September, 1998. Hence, WO99/58660 is not prior art under 35 U.S.C. 102(a).


Hence, Applicants respectfully request that this rejection be withdrawn.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-1618P2C6). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

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